

<b>Civil Action Number</b>	<b>Exhibit A - Jerry Blaivas, M.D.</b>
2:12-cv-02027	Gullett et al v. Johnson & Johnson et al
2:12-cv-02134	Elaine Anderson v. Johnson & Johnson, Inc. et al
2:12-cv-02191	Angelia M. & Manuel M. Ramirez v. Johnson & Johnson, et al.
2:12-cv-02192	Mary Frances & Joseph L. Richard v. Johnson & Johnson, et al.
2:12-cv-02193	Dawn & David Sequino v. Johnson & Johnson, et al.
2:12-cv-02198	Mary & Jeffrey Ward v. Johnson & Johnson, et al.
2:12-cv-02199	Leslie Warner v. Johnson & Johnson, et al.
2:12-cv-02200	Judy Haddon v. Johnson & Johnson, et al.
2:12-cv-02251	Kathy & Joseph Birt v. Ethicon, et al
2:12-cv-02257	Patricia & Martin, Jr. Kuks v. Ethicon, et al
2:12-cv-02264	Charlotte A. & Troy Day v. Ethicon, et al
2:12-cv-02283	Linda G. Braden & Greg Combs v. Johnson & Johnson, et al.
2:12-cv-02315	Karen Conley v. Ethicon, et al
2:12-cv-02316	Helen Harper v. Ethicon, et al
2:12-cv-02374	Helen Van Wyck Johnson & Johnson, et al.
2:12-cv-02412	Bonnie & Calvin Huggins v. Ethicon, et al
2:12-cv-02414	Norma & Larry Carroll v. Johnson & Johnson, et al.
2:12-cv-02424	Kimberly Stevens v. Johnson & Johnson, et al.
2:12-cv-02446	Cynthia & Raymond, Sr. Falcon v. Ethicon, et al
2:12-cv-02448	Melissa Mincey v. Ethicon, et al
2:12-cv-02478	Donna & Earl Matthews v. Johnson & Johnson, et al.
2:12-cv-02485	Donna Murphy v. Johnson & Johnson, et al.
2:12-cv-02489	Joanne Phillips v. Johnson & Johnson, et al.
2:12-cv-02512	Linda Madding v. Ethicon, et al
2:12-cv-02532	Rhonda Cooper v. Ethicon, et al

Civil Action Number	Case
2:12-cv-02565	Patsy & Howard Mays v. Johnson & Johnson, et al
2:12-cv-02581	Anita Fisher v. Johnson & Johnson, et al
2:12-cv-02584	Trina Hill v. Ethicon, et al
2:12-cv-02633	Kandy P. & Rick Dotson v. Johnson & Johnson, et al
2:12-cv-02634	Ila Cosgray v. Johnson & Johnson, et al
2:12-cv-02642	Tabitha Williamson v. Johnson & Johnson, et al
2:12-cv-02657	Lori & Duane Morse v. Johnson & Johnson, et al
2:12-cv-02662	Joyce & William Thomas v. Johnson & Johnson, et al
2:12-cv-02663	Debbie & Charles Tomlinson v. Johnson & Johnson, et al
2:12-cv-02672	Deborah & Steven Ray, Jr. Young v. Johnson & Johnson, et al
2:12-cv-02687	Kathleen & Glennon Toennies v. Ethicon, et al
2:12-cv-02688	Victoria Soltanshahi v. Ethicon, et al
2:12-cv-02689	Karen A. & Thomas F. Lyszcarz v. Ethicon, et al
2:12-cv-02690	Barbara Lawyer-Johnson v. Ethicon, et al
2:12-cv-02716	Brenda Simpson v. Johnson & Johnson, et al
2:12-cv-02741	Sara & Terrance Bell v. Ethicon, et al
2:12-cv-02742	Jennifer & Hilario Aguilar v. Ethicon, et al
2:12-cv-02797	Susan & Hubert Jones v. Ethicon, et al
2:12-cv-02799	Susan Clones v. Ethicon, et al
2:12-cv-02802	Kathy Robertson v. Ethicon, et al
2:12-cv-02805	Donna & Joe Moosman v. Ethicon, et al
2:12-cv-02829	Kimberly Hill v. Ethicon, et al
2:12-cv-02865	Mattie J. Brooks v. Johnson & Johnson, et al
2:12-cv-02879	Lisa A. Russell v. Ethicon, et al
2:12-cv-02921	Susan D. Bartley v. Ethicon, et al
2:12-cv-02934	Dawn Cordero-Cullipher v. Johnson & Johnson, et al
2:12-cv-02943	Kathy Blake v. Johnson & Johnson, et al
2:12-cv-02951	Brenda J. & Barry Wooden v. Johnson & Johnson, et al

Civil Action Number	Case
2:12-cv-02955	Anne M. Currie v. Johnson & Johnson, et al
2:12-cv-02956	Audrey & Theron Smallridge v. Johnson & Johnson, et al
2:12-cv-02959	Jamie & Steven Rutherford v. Ethicon, et al
2:12-cv-02971	Janice & Don Fields v. Johnson & Johnson, et al
2:12-cv-02975	Grethel Taylor v. Johnson & Johnson, et al
2:12-cv-02989	Shannon L. Smith v. Ethicon, et al
2:12-cv-02991	Susan & Simon Thomas Grizzle v. Ethicon, et al
2:12-cv-02994	Vicki & Randall Trammell v. Ethicon, et al
2:12-cv-02999	Mary Allmon v. Ethicon, et al
2:12-cv-03013	Deborah & Robert Kissel v. Johnson & Johnson, et al
2:12-cv-03074	April & Danny Berry v. Ethicon, et al
2:12-cv-03076	Stephanie & Davin Booher v. Ethicon, et al
2:12-cv-03078	Araceli Baez v. Ethicon, et al
2:12-cv-03085	Mary Diana Book v. Ethicon, et al
2:12-cv-03091	Shirlene Franklin v. Ethicon, et al
2:12-cv-03097	Deborah & Tony Mattingly v. Ethicon, et al
2:12-cv-03108	Melissa Moore v. Ethicon, et al
2:12-cv-03118	Carol Noffsinger v. Johnson & Johnson, et al
2:12-cv-03119	Glenna T. Hensley v. Ethicon, et al
2:12-cv-03122	Kimberly & Glen A. Martello v. Ethicon, et al
2:12-cv-03123	Tammy Webb-Henson v. Ethicon, et al
2:12-cv-03124	Katherine & Henry, II Smallwood v. Ethicon, et al
2:12-cv-03129	Kelly L. & John D. White v. Ethicon, et al
2:12-cv-03131	Sara Camille Jones v. Ethicon, et al
2:12-cv-03136	Christine & Joseph Webb v. Ethicon, et al
2:12-cv-03145	Tracy & Kevin Woosley v. Johnson & Johnson, et al
2:12-cv-03162	Joann S. Bradley v. Ethicon, et al
2:12-cv-03163	Geraldean Gaylor v. Johnson & Johnson, et al
2:12-cv-03166	Christine Walker v. Ethicon, et al

EXHIBIT B

IN THE UNITED STATES DISTRICT COURT  
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

CHARLESTON DIVISION

IN RE:      ETHICON INC.  
PELVIC REPAIR SYSTEMS  
PRODUCT LIABILITY LITIGATION

MDL No. 2327

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THIS DOCUMENT RELATES TO:

Cases Identified in the Exhibit  
Attached Hereto

**MEMORANDUM OPINION AND ORDER**  
(*Daubert Motion re: Jerry Blaivas, M.D.*)

Pending before the court is the Motion to Exclude Certain General Opinions of Jerry Blaivas, M.D. [ECF No. 2038] filed by defendants Johnson & Johnson and Ethicon, Inc. (collectively “Ethicon”). The Motion is now ripe for consideration because briefing is complete.

**I.      Background**

This case resides in one of seven MDLs assigned to me by the Judicial Panel on Multidistrict Litigation concerning the use of transvaginal surgical mesh to treat pelvic organ prolapse (“POP”) and stress urinary incontinence (“SUI”). In the seven MDLs, there are more than 75,000 cases currently pending, approximately 30,000 of which are in this MDL.

In this MDL, the court’s tasks include “resolv[ing] pretrial issues in a timely and expeditious manner” and “resolv[ing] important evidentiary disputes.” Barbara J. Rothstein & Catherine R. Borden, Fed. Judicial Ctr., *Managing Multidistrict*

*Litigation in Products Liability Cases* 3 (2011). To handle motions to exclude or to limit expert testimony pursuant to *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), the court developed a specific procedure. In Pretrial Order (“PTO”) No. 217, the court instructed the parties to file only one *Daubert* motion per challenged expert, to file each motion in the main MDL—as opposed to the individual member cases—and to identify which cases would be affected by the motion. PTO No. 217, at 4.<sup>1</sup>

## II. Preliminary Matters

Before plunging into the heart of the Motion, a few preliminary matters need to be addressed.

I am compelled to comment on the parties’ misuse of my previous *Daubert* rulings on several of the experts offered in this case. *See generally Sanchez v. Bos. Sci. Corp.*, No. 2:12-cv-05762, 2014 WL 4851989 (S.D. W. Va. Sept. 29, 2014); *Tyree v. Bos. Sci. Corp.*, 54 F. Supp. 3d 501 (S.D. W. Va. 2014); *Eghnayem v. Bos. Sci. Corp.*, 57 F. Supp. 3d 658 (S.D. W. Va. 2014). The parties have, for the most part, structured their *Daubert* arguments as a response to these prior rulings, rather than an autonomous challenge to or defense of expert testimony based on its reliability and relevance. In other words, the parties have comparatively examined expert testimony and have largely overlooked *Daubert’s* core considerations for assessing expert

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<sup>1</sup> Ethicon identified the Wave 1 cases affected by this Motion in its attached Exhibit A [ECF No. 2038-1], which the court has attached to this Memorandum Opinion and Order. At the time of transfer or remand, the parties will be required to designate relevant pleadings from MDL 2327, including the motion, supporting memorandum, response, reply, and exhibits referenced herein.

testimony. Although I recognize the tendency of my prior evidentiary determinations to influence subsequent motions practice, counsels' expectations that I align with these previous rulings when faced with a different record are misplaced, especially when an expert has issued new reports and given additional deposition testimony.

Mindful of my role as gatekeeper for the admission of expert testimony, as well as my duty to "respect[ ] the individuality" of each MDL case, *see In re Phenylpropanolamine Prods. Liab. Litig.*, 460 F.3d 1217, 1231 (9th Cir. 2006), I refuse to credit *Daubert* arguments that simply react to the court's rulings in *Sanchez* and its progeny. Indeed, I feel bound by these earlier cases only to the extent that the expert testimony and *Daubert* objections presented to the court then are identical to those presented now. Otherwise, I assess the parties' *Daubert* arguments anew. That is, in light of the particular expert testimony and objections currently before me, I assess "whether the reasoning or methodology underlying the testimony is scientifically valid" and "whether that reasoning or methodology properly can be applied to the facts in issue." *Daubert*, 509 U.S. at 592–93. Any departure from *Sanchez*, *Eghnayem*, or *Tyree* does not constitute a "reversal" of these decisions and is instead the expected result of the parties' submission of updated expert reports and new objections to the expert testimony contained therein.

Finally, I have attempted to resolve all possible disputes before transfer or remand, including those related to the admissibility of expert testimony pursuant to *Daubert*. Nevertheless, in some instances I face *Daubert* challenges where my interest in accuracy counsels reserving ruling until the reliability of the expert

testimony may be evaluated at trial. At trial, the expert testimony will be tested by precise questions asked and answered. The alternative of live *Daubert* hearings is impossible before transfer or remand because of the numerosity of such motions in these seven related MDLs. As these MDLs have grown and the expert testimony has multiplied, I have become convinced that the critical gatekeeping function permitting or denying expert testimony on decisive issues in these cases is best made with a live expert on the witness stand subject to vigorous examination.

In the course of examining a multitude of these very similar cases involving the same fields of expertise, I have faced irreconcilably divergent expert testimony offered by witnesses with impeccable credentials, suggesting, to me, an unreasonable risk of unreliability. The danger—and to my jaded eye, the near certainty—of the admission of “junk science” looms large in this mass litigation.

The parties regularly present out-of-context statements, after-the-fact rationalizations of expert testimony, and incomplete deposition transcripts. This, combined with the above-described practice of recycling expert testimony, objections, and the court’s prior rulings, creates the perfect storm of obfuscation. Where further clarity is necessary, I believe it can only be achieved through live witness testimony—not briefing—I will therefore reserve ruling until expert testimony can be evaluated firsthand.

### **III. Legal Standard**

By now, the parties should be intimately familiar with Rule 702 of the Federal Rules of Evidence and *Daubert*, so the court will not linger for long on these

standards.

Expert testimony is admissible if the expert is qualified and if his or her expert testimony is reliable and relevant. Fed. R. Evid. 702; *see also Daubert*, 509 U.S. at 597. An expert may be qualified to offer expert testimony based on his or her “knowledge, skill, experience, training, or education.” Fed. R. Evid. 702. Reliability may turn on the consideration of several factors:

- (1) whether a theory or technique can be or has been tested;
- (2) whether it has been subjected to peer review and publication;
- (3) whether a technique has a high known or potential rate of error and whether there are standards controlling its operation; and
- (4) whether the theory or technique enjoys general acceptance within a relevant scientific community.

*Cooper v. Smith & Nephew, Inc.*, 259 F.3d 194, 199 (4th Cir. 2001) (citing *Daubert*, 509 U.S. at 592–94). But these factors are neither necessary to nor determinative of reliability in all cases; the inquiry is flexible and puts “principles and methodology” above conclusions and outcomes. *Daubert*, 509 U.S. at 595; *see also Kumho Tire Co. v. Carmichael*, 525 U.S. 137, 141, 150 (1999). Finally, and simply, relevance turns on whether the expert testimony relates to any issues in the case. *See, e.g., Daubert*, 509 U.S. at 591–92 (discussing relevance and helpfulness).

At bottom, the court has broad discretion to determine whether expert testimony should be admitted or excluded. *Cooper*, 259 F.3d at 200.

#### **IV. Discussion**

Dr. Blavais is a urologist with extensive experience treating patients with complications related to mesh sling surgery.

### a. Alternative Design and Products

*First*, Ethicon argues that Dr. Blaivas should not be permitted to testify that alternative procedures are safer than Ethicon's mesh products. Expert testimony on this subject, Ethicon claims, is not relevant. The relevance of this expert testimony is better decided on a case-by-case basis. Accordingly, I RESERVE ruling on this matter until trial.

Ethicon also objects to the reliability of Dr. Blaivas's expert testimony about whether alternative procedures are safer than Ethicon's mesh products. In my view, the reliability of this expert testimony is heavily dependent on Dr. Blaivas's clinical experiences.<sup>2</sup>

In the abstract, experience—on its own or accompanied by little else—is a reliable basis for expert testimony. *See Kumho*, 526 U.S. at 156. But the reliability inquiry must probe into the relationship between the experience and the expert testimony:

If the witness is relying solely or primarily on experience, then the witness must explain how that experience leads to the conclusion reached, why that experience is a sufficient basis for the opinion, and how that experience is reliably applied to the facts.

Fed. R. Evid. 702 advisory committee's note to 2000 amendment. Here, the court does not have enough information to judge the reliability or relevance of Dr. Blaivas's particular experience.

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<sup>2</sup> This is especially so because, while Dr. Blaivas reviewed medical literature, he has characterized the medical literature concerning the safety of mesh devices as "poor."

In this specific context, I am without sufficient information at this time to draw the fine line between reliable and unreliable expert testimony based primarily on an expert's clinical experiences. Accordingly, I **RESERVE** ruling until further testimony may be offered and evaluated firsthand at trial.

*Second*, Ethicon claims Dr. Blaivas is not qualified to offer expert testimony about alternative designs (e.g., mesh with larger pore size or less weight). I do not need to opine on his qualifications because this aspect of his testimony is clearly unreliable. In an effort to show this expert testimony is reliable, the plaintiffs offered up an article entitled *Safety Considerations for Synthetic Sling Surgery*, which Dr. Blaivas co-authored, and noted Dr. Blaivas's reliance on the sources cited. But those sources concern hernia repair mesh and were insufficient to allow, as the authors put it, "any meaningful conclusions." Resp. Ex. 2, at 12 [ECF No. 2176-2]. Yet Dr. Blaivas never explains how this uncertainty expressed in a 2015 article—which contradicts the expert testimony he intends to offer—has been dispelled. Nor does Dr. Blaivas explain the import of the medical literature he cites to support his expert testimony. Upon review of the record, I am not satisfied that Dr. Blaivas's opinion is reliable. Ethicon's Motion is **GRANTED** on this point.

*Third*, Ethicon challenges the reliability of Dr. Blaivas's expert testimony about mechanical-cut and laser-cut mesh. In his report, Dr. Blaivas cites to internal Ethicon documents to support this opinion, which offer some support. But like the testimony above, the lynchpin of Dr. Elliott's testimony seems to be his experience. And as noted above, I am without information sufficient to assess whether this is a

reliable foundation. So I **RESERVE** ruling until further testimony may be offered and evaluated firsthand at trial.

*Fourth*, Ethicon challenges the reliability of Dr. Blaivas's expert testimony about the implantation approach and that an alternative implantation approach would be safer. The plaintiffs focus on what they perceive as the shortcomings in Ethicon's argument, and they fail to explain why this expert testimony is reliable. Given no reason to find this expert testimony reliable, Ethicon's Motion is **GRANTED** on this point.

*Fifth*, Ethicon challenges the reliability of Dr. Blaivas's expert testimony about the size of the surgical trocars and the implantation technique. Neither article cited in support of this expert testimony by Dr. Blaivas supports this position, and Dr. Blaivas does not explain why these articles support his position. The same is true for the article referenced by the plaintiffs in response to Ethicon's argument—an article cited in connection with a different proposition in Dr. Blaivas's report. Accordingly, Ethicon's Motion is **GRANTED** on this point.

*Sixth*, Ethicon challenges the reliability of Dr. Blaivas's expert testimony about mesh length. The plaintiffs do not present any argument discussing why it is admissible (i.e., reliable). I will not make arguments for the plaintiffs; therefore, Ethicon's Motion is **GRANTED** on this point.

#### b. Warnings

Ethicon claims Dr. Blaivas is not qualified to offer expert testimony about product warnings, which includes expert testimony about the adequacy of the

relevant Instructions for Use (“IFU”). According to Ethicon, Dr. Blaivas is not an expert in the development of warning labels and thus is not qualified to offer expert testimony about warnings. Dr. Blaivas is not an expert in the development of warning labels. While an expert who is a urologist may testify about the specific risks of implanting mesh and whether those risks appeared on the relevant IFU, the same expert must possess additional expertise to offer expert testimony about what information should or should not be included in an IFU. *Wise v. C. R. Bard, Inc.*, No. 2:12-cv-1378, 2015 WL 521202, at \*14 (S.D. W. Va. Feb. 7, 2015). Dr. Blaivas does not possess the additional expertise to offer expert testimony about what an IFU should or should not include. Accordingly, Dr. Blaivas’s expert testimony about these matters is **EXCLUDED**.

**c. Safety and Efficacy**

Ethicon challenges the reliability of Dr. Blaivas’s expert testimony about safety and efficacy and complication rates by pointing out numerous perceived flaws in the foundation of Dr. Blaivas’s expert testimony. Two primary problems render this expert testimony unreliable. First, Dr. Blaivas continues to rely quite heavily on complications rates this court has excluded time and again. *E.g., Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 691, 721 (S.D. W. Va. 2014). In *Huskey*, I excluded this expert testimony because “Dr. Blaivas did not explain his methodology and admitted that it was impossible to calculate an accurate complication rate.” *Id.* He has not remedied these shortcomings. Second, Dr. Blaivas does not provide a reasonable explanation for his disagreement with guidelines that he helped author and that conclude mesh

products are suitable surgical options. *See, e.g., Bethune v. Bos. Sci. Corp.*, No. 2:13-cv-6199, 2016 WL 2983697, at \*4 (S.D. W. Va. May 20, 2016) (noting an expert's methodology "may be flawed if he does not provide an adequate explanation for why he disagrees with [contrary] studies"). Accordingly, the expert testimony is **EXCLUDED**.

**d. Properties**

Ethicon asks the court to exclude Dr. Blaivas's biomaterials opinions related to mesh degradation, shrinkage, and other deformations because Dr. Blaivas is unqualified and his opinions are unreliable. The plaintiffs make no response to the specific reliability challenge and I decline to raise counterarguments on their behalf. Ethicon's Motion on this matter is **GRANTED** and Dr. Blaivas's opinions on biomaterials are **EXCLUDED**. I thus find it unnecessary to address his qualifications.

**e. Complications**

Ethicon seeks to exclude Dr. Blaivas's testimony regarding cancer and death complications that no plaintiff in these cases has suffered. Evidence of complications that a plaintiff did not experience is irrelevant and lacking in probative value. Accordingly, to the extent that Dr. Blaivas seeks to opine on complications that no plaintiff in this wave of cases has suffered, such testimony is **EXCLUDED**.

Ethicon also challenges Dr. Blaivas's use of the terms "chronic mesh pain syndrome," "mesh cripples," and "Meshology" because these terms are inflammatory and prejudicial. The plaintiffs have sufficiently demonstrated that the term "chronic mesh pain syndrome" is used in scientific literature, as Dr. Blaivas cites to a chapter

entitled “Pain Complications of Mesh Surgery” in the academic textbook *Complications of Female Incontinence and Pelvic Reconstructive Surgery*. Ethicon’s Motion regarding Dr. Blaivas’s use of the term “chronic mesh pain syndrome” is **DENIED**. I agree that terms such as “mesh cripples” and “Meshology” are inflammatory and unduly prejudicial, and their use in testimony is **EXCLUDED**.

**f. Product Testing**

Ethicon claims Dr. Blaivas is not qualified to offer opinions about product testing Ethicon should have conducted and about what such testing would have revealed. As I have found before, “[t]here is no indication in the record that Dr. Blaivas has any experience or knowledge on the appropriate testing a medical device manufacturer should undertake.” *Huskey*, 29 F. Supp. 3d at 723. Because Dr. Blaivas is not qualified to offer expert testimony of this sort, his expert testimony on this matter is **EXCLUDED**.

**g. Industry Bias and Collusion**

In his reports, Dr. Blaivas criticizes the medical literature about mesh products, claiming some studies are biased. If Ethicon seeks to challenge Dr. Blaivas’s allegations of bias as to these studies, it may do so on cross-examination. *See Tyree*, 54 F. Supp. 3d at 559. To the extent Ethicon seeks to exclude these matters, its Motion is **DENIED**.

Dr. Blaivas also offers his opinion that Ethicon colluded with other manufacturers to influence reimbursement. Ethicon asks the court to exclude this opinion. The plaintiffs do not offer any response. Accordingly, Ethicon’s Motion is

GRATNED as to this matter.

#### V. Recurring Issues

Many of the *Daubert* motions filed in this MDL raise the same or similar objections.

One particular issue has been a staple in this litigation, so I find it best to discuss it in connection with every expert. A number of the *Daubert* motions seek to exclude FDA testimony and other regulatory or industry standards testimony. To the extent this Motion raises these issues it is **GRANTED in part** and **RESERVED in part** as described below.

I have repeatedly excluded evidence regarding the FDA's section 510(k) clearance process in these MDLs, and will continue to do so in these cases, a position that has been affirmed by the Fourth Circuit. *In re C. R. Bard, Inc.*, 81 F.3d 913, 921–23 (4th Cir. 2016) (upholding the determination that the probative value of evidence related to section 510(k) was substantially outweighed by its possible prejudicial impact under Rule 403). Because the section 510(k) clearance process does not speak directly to safety and efficacy, it is of negligible probative value. *See In re C. R. Bard*, 81 F.3d at 920 (“[T]he clear weight of persuasive and controlling authority favors a finding that the 510(k) procedure is of little or no evidentiary value.”). Delving into complex and lengthy testimony about regulatory compliance could inflate the perceived importance of compliance and lead jurors “to erroneously conclude that regulatory compliance proved safety.” *Id.* at 922. Accordingly, expert testimony related to the section 510(k) process, including subsequent enforcement

actions and discussion of the information Ethicon did or did not submit in its section 510(k) application, is **EXCLUDED**. For the same reasons, opinions about Ethicon's compliance with or violation of the FDA's labeling and adverse event reporting regulations are **EXCLUDED**. In addition to representing inappropriate legal conclusions, such testimony is not helpful to the jury in determining the facts at issue in these cases and runs the risk of misleading the jury and confusing the issues. Insofar as this Motion challenges the FDA-related testimony discussed here, the Motion is **GRANTED**.

A number of experts also seek to opine on Ethicon's compliance with design control and risk management standards. Some of this testimony involves the FDA's quality systems regulations, and some—likely in an attempt to sidestep my anticipated prohibition on FDA testimony—involve foreign regulations and international standards. I find all of this proposed testimony of dubious relevance. Although these standards relate to how a manufacturer should structure and document risk assessment, the standards do not appear to mandate any particular design feature or prescribe the actual balance that must be struck in weighing a product's risk and utility. Nor is it clear that the European and other international standards discussed had any bearing on the U.S. medical device industry when the device in question was being designed.

Nevertheless, because the nuances of products liability law vary by state, I will refrain from issuing a blanket exclusion on design process and control standards testimony, whether rooted in the FDA or otherwise. Each standard must be assessed

for its applicability to the safety questions at issue in this litigation, consistent with state law. I am without sufficient information to make these findings at this time. Accordingly, I **RESERVE** ruling on such matters until a hearing, where the trial judge will have additional context to carefully evaluate the relevance and potential prejudicial impact of specific testimony.

Similarly, I doubt the relevance of testimony on the adequacy of Ethicon's clinical testing and research, physician outreach, or particular product development procedures and assessments otherwise not encompassed by the above discussion. Again, such matters seem to say very little about the state of the product itself (i.e., whether or not it was defective) when it went on the market. But because the scope of relevant testimony may vary according to differences in state products liability law, I **RESERVE** ruling on such matters until they may be evaluated in proper context at a hearing before the trial court before or at trial.

Additional—and more broad—matters also warrant mention. While some of these concerns may not apply to this particular expert, these concerns are raised so frequently that they are worth discussing here.

*First*, many of the motions seek to exclude state-of-mind and legal-conclusion expert testimony. Throughout these MDLs, the court has prohibited the parties from using experts to usurp the jury's fact-finding function by allowing testimony of this type, and I do the same here. *E.g., In re C. R. Bard, Inc.*, 948 F. Supp. 2d 589, 611 (S.D. W. Va. 2013); *see also, e.g., United States v. McIver*, 470 F.3d 550, 562 (4th Cir. 2006) ("[O]pinion testimony that states a legal standard or draws a legal conclusion

by applying law to the facts is generally inadmissible.”); *In re Rezulin Prods. Liab. Litig.*, 309 F. Supp. 2d 531, 546 (S.D.N.Y. 2004) (“Inferences about the intent and motive of parties or others lie outside the bounds of expert testimony.”). Additionally, an expert may not offer expert testimony using “legal terms of art,” such as “defective,” “unreasonably dangerous,” or “proximate cause.” *See Perez v. Townsend Eng’g Co.*, 562 F. Supp. 2d 647, 652 (M.D. Pa. 2008).

*Second*, and on a related note, many of the motions seek to prohibit an expert from parroting facts found in corporate documents and the like. I caution the parties against introducing corporate evidence through expert witnesses. Although an expert may testify about his review of internal corporate documents solely for the purpose of explaining the basis for his or her expert opinions—assuming the expert opinions are otherwise admissible—he or she may not offer testimony that is solely a conduit for corporate information.

*Third*, many of the motions also ask the court to require an expert to offer testimony consistent with that expert’s deposition or report or the like. The court will not force an expert to testify one way or another. To the extent an expert offers inconsistent testimony, the matter is more appropriately handled via cross-examination or impeachment as appropriate and as provided by the Federal Rules of Evidence.

*Fourth*, in these *Daubert* motions, the parties have addressed tertiary evidentiary matters like whether certain statements should be excluded as hearsay. The court will not exclude an expert simply because a statement he or she discussed

may constitute hearsay. *Cf. Daubert*, 509 U.S. at 595. Hearsay objections are more appropriately raised at trial.

Finally, in some of the *Daubert* motions, without identifying the specific expert testimony to be exclude, the parties ask the court to prevent experts from offering other expert testimony that the moving party claims the expert is not qualified to offer. I will not make speculative or advisory rulings. I decline to exclude testimony where the party seeking exclusion does not provide specific content or context.

## VI. Conclusion

The court **DENIES** in part, **GRANTS** in part, and **RESERVES** in part the Motion to Exclude Certain General Opinions of Jerry Blaivas, M.D. [ECF No. 2038].

The court **DIRECTS** the Clerk to file a copy of this Memorandum Opinion and Order in 2:12-md-2327 and in the Ethicon Wave 1 cases identified in the Exhibit attached hereto.

ENTER: August 26, 2016



JOSEPH R. GOODWIN  
UNITED STATES DISTRICT JUDGE

**IN THE UNITED STATES DISTRICT COURT  
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA  
CHARLESTON DIVISION**

**IN RE: ETHICON, INC. PELVIC REPAIR  
SYSTEM PRODUCTS LIABILITY  
LITIGATION**

**THIS DOCUMENT RELATES TO  
ETHICON WAVE 1 CASES**

**Master File No. 2:12-MD-02327  
MDL No. 2327**

**JOSEPH R. GOODWIN  
U.S. DISTRICT JUDGE**

**EXHIBIT A TO MOTION TO EXCLUDE CERTAIN  
GENERAL OPINIONS OF JERRY G. BLAIVAS, M.D.**

**ALL CASES PERTINENT TO MOTION**

1. *Joan Adams v. Ethicon, Inc., et al.*, Civil Action No. 2:12-cv-01203 (Prolift);
2. *Marty Babcock v. Ethicon, Inc., et al.*, Civil Action No. 2:12-cv-01052 (TVT);
3. *Daphne Barker, et al. v. Ethicon, Inc., et al.*, Civil Action No. 2:12-cv-00899 (TVT);
4. *Dorothy Baugher v. Ethicon, Inc., et al.*, Civil Action No. 2:12-cv-01053 (TVT-O);
5. *Melissa Clayton, et al. v. Ethicon, Inc., et al.*, Civil Action No. 2:12-cv-00489 (Prolift);
6. *Constance Daino, et al. v. Ethicon, Inc., et al.*, Civil Action No. 2:12-cv-01145 (TVT);
7. *Lois Durham, et al. v. Ethicon, Inc., et al.*, Civil Action No. 2:12-cv-00760 (Prolift & TVT-O);
8. *Monica Freitas, et al. v. Ethicon, Inc., et al.*, Civil Action No. 2:12-cv-01146 (TVT);
9. *Beth Harter, et al. v. Ethicon, Inc., et al.*, Civil Action No. 2:12-cv-00737 (Prosima & TVT-O);
10. *Jeanie Holmes v. Ethicon, Inc., et al.*, Civil Action No. 2:12-cv-01206 (TVT-O);
11. *Mary Holzerland, et al. v. Ethicon, Inc., et al.*, Civil Action No. 2:12-cv-00875 (TVT-Secur);
12. *Myndal Johnson v. Ethicon, Inc., et al.*, Civil Action No. 2:12-cv-00498 (TVT);
13. *Holly Jones, et al. v. Ethicon, Inc., et al.*, Civil Action No. 2:12-cv-00443 (TVT);

14. *Deborah Lynn Joplin v. Ethicon, Inc., et al.*, Civil Action No. 2:12-cv-00787 (TVT-O);
15. *Beverly Kivel v. Ethicon, Inc., et al.*, Civil Action No. 2:12-cv-00591 (Gynemesh PS);
16. *Paula Kriz, et al. v. Ethicon, Inc., et al.*, Civil Action No. 2:12-cv-00938 (Gynemesh PS & TVT-O);
17. *Alfreda Lee, et al. v. Ethicon, Inc., et al.*, Civil Action No. 2:12-cv-01013 (TVT-Secur);
18. *Angela Morrison, et al. v. Ethicon, Inc., et al.*, Civil Action No. 2:12-cv-00800 (TVT);
19. *Miranda Patterson v. Ethicon, Inc., et al.*, Civil Action No. 2:12-cv-00481 (TVT-O);
20. *Patti Ann Phelps v. Ethicon, Inc., et al.*, Civil Action No. 2:12-cv-01171 (TVT);
21. *Maria Eugenia Quijano v. Ethicon, Inc., et al.*, Civil Action No. 2:12-cv-00799 (TVT);
22. *Jennifer Reyes, et al. v. Ethicon, Inc., et al.*, Civil Action No. 2:12-cv-00939 (TVT);
23. *Ana Ruebel v. Ethicon, Inc., et al.*, Civil Action No. 2:12-cv-00663 (Prolift Total & TVT-O);
24. *Denise Sacchetti v. Ethicon, Inc., et al.*, Civil Action No. 2:12-cv-01148 (TVT-O);
25. *Stacy Shultis, et al. v. Ethicon, Inc., et al.*, Civil Action No. 2:12-cv-00654 (TVT-O);
26. *Susan Thaman v. Ethicon, Inc., et al.*, Civil Action No. 2:12-cv-00279 (Prolift Anterior & TVT-Secur);
27. *Laura Waynick, et al. v. Ethicon, Inc., et al.*, Civil Action No. 2:12-cv-01151 (TVT);
28. *Rebecca Wheeler, et al. v. Ethicon, Inc., et al.*, Civil Action No. 2:12-cv-01088 (TVT-O);
29. *Virginia White, et al. v. Ethicon, Inc., et al.*, Civil Action No. 2:12-cv-00958 (Gynemesh PS & TVT-R); and
30. *Kathleen Wolfe v. Ethicon, Inc., et al.*, Civil Action No. 2:12-cv-00337 (TVT).

\* Defendants reserve the right to supplement this list should any other plaintiff be allowed to designate Dr. Blaivas as general causation expert in MDL Wave 1.

## Exhibit C

### Index of Relevant Pleadings related to Jerry Blaivas, M.D.

Judge Goodwin instituted a series of Waves in MDL 2327 wherein he identified hundreds of cases per Wave subject to discovery and motion practice deadlines. As part of the Wave process, Judge Goodwin required parties to file one general causation *Daubert* motion per expert per Wave in the main MDL, rather than in each individual Wave case. Parties were required to identify the cases in each Wave to which a particular *Daubert* motion applied. The court has identified below, the relevant *Daubert* pleadings filed in each Wave (and in many cases ultimately adopted in subsequent Waves) for the court receiving this case on remand or transfer.

Wave 1	Date	WVSD ECF No.
Motion	4/21/16	2038
Memorandum	4/21/16	2040
Response	5/9/16	2176
Reply	5/16/16	2213
Mem Op & Ord	8/26/16	2667

Wave 2	Date	WVSD ECF No.	Comment
Motion	7/21/16	2465	Adopts ECF No. 2038
Memorandum	7/21/16	2465	Adopts ECF No. 2040
Response	8/8/16	2500	Adopts ECF No. 2176
Reply	8/18/16	2624	Adopts ECF No. 2213
Mem Op & Ord	3/31/17	3565	Adopts ECF No. 2667

Wave 3	Date	WVSD ECF No.	Comment
Motion	9/19/16	2819	Does not adopt
Memorandum	9/19/16	2822	Does not adopt
Response	10/11/16	2947	Does not adopt
Reply	10/20/16	3016	Does not adopt